

### REMARKS

Applicant has amended claims 1, 14, 19, 21, and 23 to correct typographical errors and to clarify the relationship between elements. A marked up copy of the amended claims is attached as Appendix A. Applicant has also added new claims 30 and 31. Basis for the amendment and new claims can be found throughout the specification, drawings, and originally filed claims, specifically page 6, lines 22 to 25 and Figure 5.

### ELECTION OF INVENTION

The Examiner also restricted the claims under 35 U.S.C. § 121 to either Group I, claims 1-5 and 14-18 drawn to an apparatus and Group II, claims 6-13 drawn to a method. Applicant hereby elects Group I, claims 1-5 and 14-18 drawn to an apparatus. Claims 6-13 were previously cancelled in a Preliminary Amendment filed August 19, 2002.

### 35 U.S.C. § 112

Claims 21 and 23 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant has hereby amended claims 21 and 23 to replace the phrase "the crystal growth solution" with the phrase "a crystal growth solution." The term "crystal growth solution" now has proper antecedent basis. Accordingly, Applicant respectfully requests withdrawal of the rejection.

### 35 U.S.C. § 102

Claims 14-18 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Heilig et al. (U.S. Patent No. 5,266,284). Applicant respectfully traverses and requests reconsideration.

Applicant respectfully submits that the Heilig reference does not describe each and every element of the claimed invention. Claims 14-18 are directed to a device in which there is a reservoir unit, a channel unit, and a selection unit, with both the channel unit and selection unit rotatable to give the desired alignment between the reservoir chamber and the crystal growth solution. In contrast, in the device described by the Heilig reference, only the unit containing the reservoirs, unit 112, is rotatably disposed with respect to any of the other parts. Col. 4, lines 59-62. The function of the unit 112 is that, upon rotation, a protein solution will be exposed to either reservoir solution 132 or 134, or partially to both. The Heilig reference does not describe or suggest a channel unit comprising at least one discrete

channel wherein the channel unit can rotate to align the reservoir chamber, the discrete channel, and a separate selection unit.

Additionally, the Examiner seems to be confusing the recesses of the device of the Heilig reference as reading on both the channel unit and the selection unit. Page 4, second paragraph of the Office Action. The presently claimed channel unit provides at least one discrete channel configured to control the rate of vapor diffusion between a reservoir solution and a crystal growth solution. The selection unit, in contrast, has an opening that controls channel and/or reservoir alignment, without controlling the rate of diffusion. Therefore, recess 96 of the Heilig device cannot read upon both the channel unit and the selection unit of the present invention.

Applicant thus submits that the Heilig reference does not describe each and every element of the claimed invention and therefore withdrawal of the rejection is respectfully requested.

Claims 19-22 and 24-27 have also been rejected under 35 U.S.C. § 102(b) as being anticipated by Kim et al. (U.S. Patent No. 6,039,804). Applicant respectfully traverses and requests reconsideration.

The Kim reference does not describe each and every element of the claimed assembly of the present invention. First, the claimed assembly comprises a container for holding a reservoir solution and a device having discrete diffusion pathways. Claim 19 has been amended to clarify that the device is configured for engaging the container. Thus, the device and container are separate units. In contrast, the crystallization tray of the Kim reference comprises crystallization units having a central reservoir, four diffusion channels and four drop chambers, all as integral portions of the crystallization units. None of these portions of the Kim device are separate units, as in the claimed device.

Second, the claimed assembly comprises a device having defined therein discrete diffusion pathways. Although the assembly of the present claims also includes a seal, the diffusion pathways are defined within the device itself. The seal of the present claims is not required to form diffusion pathways. In contrast, the Kim reference describes diffusion channels 30 which are open onto the upper surface of the crystallization tray. Column 4, lines 44-46. Closed (and therefore functional) diffusion channels 30 are only formed when the seal is placed over the crystallization unit. Thus, Kim does not describe a device having defined therein discrete diffusion pathways.

Applicant thus submits that the Kim reference does not describe each and every element of the claimed invention, specifically a separate reservoir container and a

device having discrete diffusion pathways, nor does Kim describe the claimed device itself with the discrete diffusion pathways defined therein. Applicant thus requests withdrawal of the rejection.

35 U.S.C. § 103

Claims 1-4, 19-22, and 24-29 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the Kim reference in view of Knittel et al. (U.S. Patent No. 3,972,689). Applicant respectfully traverses and requests reconsideration.

When determining obviousness, both the claimed invention and the references must be taken as a whole and the references must suggest the desirability of combining elements or changing elements to provide the claimed invention. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143, n.5, 229 USPQ 182, 187, n.5 (Fed. Cir. 1986). Applicant submits that neither the Kim reference nor the Knittel reference, either alone or together, teaches the claimed invention. As discussed above, the Kim reference teaches a crystallization tray comprising a number of crystallization units. Each unit has a central reservoir, a drop chamber and a diffusion channel. However, the diffusion channel has only three sides and is open to the surface of the tray. Therefore, the channel is not a discrete diffusion pathway defined therein and cannot function to control vapor communication between the reservoir solution and the drop without a seal being applied to the crystallization unit. In contrast, the claimed device of the present invention comprises discrete diffusion pathways defined therein. A seal is not required to form the pathway, as with the device from the Kim reference.

Moreover, upon reading the Kim reference, the skilled artisan would not be motivated to change the crystallization unit of the Kim reference to produce the presently claimed device. The present device has defined diffusion pathways for controlling the rate of vapor diffusion between a crystal growth solution and a reservoir solution. As taught by the present specification, a device could be removably inserted into a chamber having a reservoir solution. A device having a specific pathways and vapor diffusion rates could be used to give optimal crystallization. Different devices with differing vapor diffusion rates may be tested to find the one providing optional crystallization. In contrast, the advantage of the crystallization tray of the Kim reference is that it comprises a single piece in which a large number of samples can be tested under the same vapor diffusion rates. Therefore, there is no teaching or motivation to modify the Kim reference to produce the device of the present invention.

Furthermore, the Knittel reference does not overcome these deficiencies. The Knittel reference teaches a sealed ampule for vapor growing inorganic crystals. A solution is placed in one end of the ampule and a capillary is inserted into the solution, allowing vapor to flow to the upper portion of the chamber along a decreasing temperature gradient. As the vapor cools, a crystal is formed in the upper tip of the ampule. The Knittel reference, however, does not teach or suggest a discrete pathway controlling the vapor diffusion rate between a crystal growth solution and a reservoir solution. Instead, in the Knittel reference there is only one sample solution. Moreover, there is no suggestion or motivation to combine the sealed, glass, vacuum ampule used for inorganic vapor crystal growth with the plastic crystallization ray of the Kim reference used for protein crystal growth. Applicant therefore requests withdrawal of the rejection.

Claims 5 and 23 have also been rejected under 35 U.S.C. § 103(a) as being unpatentable over the Kim reference in view of the Knittel reference and in further view of Roorda et al. (U.S. Patent No. 5,972,369). Applicants respectfully traverses and requests reconsideration.

As discussed above, neither the Kim reference nor the Knittel reference, either alone or together, teaches or suggests the present invention. The Roorda reference teaches an implantable delivery system having a reservoir and a delivery channel wherein the channel can contain a gel to control diffusion. In contrast, the device of the present invention is made of a porous material, not of gel-filled channels. Furthermore, there is certainly no suggestion of how the teachings of the Roorda reference, pertaining to the unrelated art of implantable delivery devices can be combined with the Kim and/or Knittel references. Therefore the Roorda reference does not overcome the deficiencies of the Kim or Knittel references and Applicant requests withdrawal of the rejection.

CONCLUSION

The claims now stand ready for allowance and such allowance is courteously solicited. Should the Examiner have any questions or wish to discuss this matter further, the Examiner is invited to call the attorney below at (317) 231-7504.

Respectfully submitted



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## APPENDIX A

Under 37 C.F.R. § 1.121(c)(1)(i), claims , 14, 19, 21, and 23 have been amended as follows:

1. (Twice Amended) A device for kinetically controlling the rate of vapor diffusion during crystal growth said device having defined therein discrete diffusion pathways, wherein said pathways control the vapor diffusion rate between a crystal growth solution and a reservoir solution, the device configured for placement between the crystal growth solution and the reservoir solution.

14. (Amended) A device for kinetically controlling the rate of vapor diffusion during crystal growth in a crystal growth solution comprising:

(a) a reservoir unit comprising at least one reservoir chamber.

(b) a channel unit comprising at least one discrete channel configured to control the rate of vapor diffusion between the reservoir chamber and the crystal growth solution; and

(c) a selection unit comprising an opening wherein the opening is large enough not to control the rate of vapor diffusion between the reservoir chamber and the crystal growth solution;

wherein [the reservoir unit,] the channel unit and the selection unit can rotate individually to align the reservoir chamber, the discrete [chamber] channel, and the opening.

19. (Amended) An assembly for aiding crystal growth, said assembly comprising:

a container for holding a reservoir solution;

a device configured for engaging the container, the device having defined therein discrete diffusion pathways; and

a seal.

21. (Amended) The assembly of claim 20 wherein the device comprises at least two channels, wherein the channels are between [the] a crystal growth solution and at least two different reservoir solutions.

23. (Amended) The assembly of claim 19 wherein the device is made of a material porous to a vapor moving between [the] a crystal growth solution and the reservoir solution.